IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SANTARUS, INC., a Delaware corporation, and THE CURATORS OF THE UNIVERSITY OF MISSOURI, a public corporation and body politic of the State of Missouri,	)	
Plaintiffs,	)	C.A. No. 07-551-GMS
v.	)	(CONSOLIDATED)
PAR PHARMACEUTICAL, INC., a Delaware corporation,	)	
Defendants	)	

DEFENDANT PAR PHARMACEUTICAL, INC.'S
OPENING CLAIM CONSTRUCTION BRIEF REGARDING
U.S. PATENT NOS. 6,489,346; 6,699,885; AND 6,645,988

Frederick L. Cottrell, III (#2555)
Steven J. Fineman (#4025)
Richards, Layton & Finger, P.A.
One Rodney Square
920 North King Street
Wilmington, DE 19801
(302) 651-7700
Cottrell@rlf.com
Fineman@rlf.com
Attorneys for Defendant

Of Counsel:
Edgar H. Haug
James K. Stronski
Bryan J. Braunel
Frommer Lawrence & Haug LLP
745 Fifth Avenue
New York, New York 10151
(212) 588-0800

Janine A. Carlan
Aziz Burgy
Timothy W. Bucknell
Arent Fox LLP
1050 Connecticut Ave., N.W.
Washington, D.C., 20036
(202) 857-6000

Dated: August 22, 2008

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Federal Cases

Federal Statutes

INTRODUCTION

Defendant Par Pharmaceutical, Inc. ("Par") submits this brief on claim construction for U.S. Patent Nos. 6,489,346 ("the '346 patent") (JA-1);[1] 6,699,885 ("the '885 patent") (JA-2); and 6,645,988 ("the '988 patent") (JA-3).[2] These patents are generally directed to non-enteric coated compositions of a proton pump inhibitor and an antacid buffer, and methods of use for treating gastric acid-related disorders. The disputed claim terms -- and Par's proposed definitions of them -- are set forth below:[3]

Disputed Claim Term	Par's Proposed Construction
"**solid pharmaceutical composition in a dosage form**"; "**solid oral pharmaceutical dosage form**"; and "**solid pharmaceutical composition for oral administration to the subject**"	A solid preparation that is administered orally to the subject. Such a preparation would not include powders that are combined with a liquid prior to administration to the subject.[4]
"**at least one optional Secondary Essential Buffer**"	at least one buffer in addition to the recited primary essential buffer, where such additional buffer is unsuitable for use alone because it produces too high a pH value leading to gastrointestinal mucosal irritation
"**combining the dosage form of claim 57 with an aqueous medium**"	requires combination with an aqueous medium prior to oral administration to the subject
"**mixing . . . with an aqueous medium**"	requires mixing with an aqueous medium prior to oral administration to the subject

Par's proposed claim constructions are based on well-established legal principles, as well as the plain meaning of the disputed claim terms, and are confirmed by the intrinsic record.

---

[1] Citations to "JA ___" refer to the Joint Appendix which will be filed pursuant to the Scheduling Order.

[2] Also in suit is U.S. Patent No. 6,780,882 ("the '882 patent") (JA-4). In addition, Par has filed a declaratory judgment claim against U.S. Patent No. 5,840,737. (D.I. 8 (07-CV-827)).

[3] The parties submitted a Joint Claim Construction Chart identifying the disputed claim terms of the patents-in-suit and the parties' respective proposed construction. (D.I. 32).

[4] A new patent, U.S. Patent No. 7,399,772 ("the '772 patent) (JA-5), recently issued to the same inventor. If the '772 patent is added to this case, Par contends that the term "solid pharmaceutical composition" would have the same interpretation as set forth here with respect to the '346, '988, and '885 patents.

NATURE AND STAGE OF THE PROCEEDING

This case is a patent-infringement suit arising out of the Hatch-Waxman Act. The case is based on Par's submissions of Abbreviated New Drug Application ("ANDA") Nos. 78-966 and 79-182 to the U.S. Food and Drug Administration ("FDA").[5] Par seeks FDA approval to market generic omeprazole and sodium bicarbonate capsules and powder for oral suspension. At issue in this case is whether the products described in Par's ANDAs would, if marketed, infringe U.S. Patent No. 5,840,737 ("the '737 patent"), the '346 patent, the '885 patent, the '988 patent, and the '882 patent (collectively "the patents-in-suit"), and whether these patents are invalid or unenforceable.[6] The patents-in-suit are exclusively licensed to Santarus, Inc. ("Santarus") by The Curators of the University of Missouri (collectively "Plaintiffs"). Santarus holds two New Drug Applications ("NDAs") for the manufacture and sale of Zegerid® capsules and Zegerid® powder for oral suspension. The '346, '988, '885 patents, as well as newly issued U.S. Patent No. 7,399,772 ("the '772 patent") (JA-5), are listed in the FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "*Orange Book*") under Zegerid® capsules. The patents-in-suit, as well as the '772 patent, are listed in the *Orange Book* under Zegerid® powder for oral suspension.

STATEMENT OF FACTS

The branded drug Zegerid® is a combination of omeprazole and sodium bicarbonate, two well-known drugs for treating conditions associated with excess acid in the stomach. Zegerid® is FDA-approved in two dosage forms: as a capsule, and as a powder for oral suspension.

---

[5] This Court consolidated Civil Action Nos. 07-CV-551 (GMS) and 07-CV-827 (GMS) on March 4, 2008.

[6] Plaintiffs are asserting claims 24, 26-27, 31-38, 49-53, 55-60, 65-69, 80-86, 90-94 and 117-118 of the '346 patent; claims 1-18, 23-25, 37-42 and 47-51 of the '885 patent; claims 1-4, 7-16 and 27-29 of the '882 patent; and claim 29 of the '988 patent. Par filed a counterclaim seeking a declaration of noninfringement, invalidity, and/or unenforceability of the '737 patent. (D.I. 8 (07-CV-827)).

Compl. ¶ 13.[7] The *Orange Book* indicates that the active ingredient omeprazole was first approved as Prilosec® on September 14, 1989 for gastric acid-related conditions. *See Orange Book* record for Prilosec, attached as Ex. A to Decl. of Fineman.[8] The other active ingredient in Zegerid®, sodium bicarbonate (baking soda), is long-established in its use as an antacid, having been described in a number of patents as being well-known for such use. *See, e.g.*, United States Patent Nos. 3,621,094 and 4,316,888, attached as Exs. B-C to Decl. of Fineman.

Omeprazole is sensitive to acid and will degrade in its presence.[9] Because of this effect, the drug Prilosec® has an enteric coat to protect the omeprazole from stomach acid.[10] However, in Zegerid®, the sodium bicarbonate protects the omeprazole by neutralizing stomach acid, thus obviating the need for an enteric coat.[11]

The patents listed in the *Orange Book* claim no more than a combination of two well-established drugs known for treating gastric acid-related conditions. *See Orange Book* "Patent and Exclusivity List" records for Zegerid®, attached as Ex. D to Decl. of Fineman. Par filed its ANDAs with the FDA seeking approval to sell generic omeprazole and sodium bicarbonate capsules and powder for oral suspension, based on bioequivalence to Santarus's corresponding Zegerid® products.[12] Pursuant to the Hatch-Waxman Act, Par certified that the patents listed in the *Orange Book* under Zegerid® are not infringed, are invalid and/or are unenforceable. Plaintiffs sued Par on September 13 and December 20, 2007, alleging that the products described in Par's ANDAs infringe certain of the *Orange Book* patents.

---

[7] References to the Complaint refer to Civil Action No. 07-827-GMS.
[8] Citations to "Ex. ___ to Decl. of Fineman" refer to the Declaration of Steven J. Fineman filed contemporaneously herewith.
[9] The '885 patent (JA-2), col. 5, ll. 9-13.
[10] *See* the '885 patent (JA-2), col. 6, ll. 39-43.
[11] *See* the '885 patent (JA-2), col. 8, ll. 48-53.
[12] *See* D.I. 9, Par's Answer and Counterclaims (07-551-GMS), ¶ 13 and D.I. 8, Amended Answer and Counterclaims (07-827-GMS), ¶ 15.

SUMMARY OF ARGUMENT

1. Based upon the ordinary meaning of the patent claim terms, the phrases "solid pharmaceutical composition in a dosage form," "solid oral pharmaceutical dosage form," and "solid pharmaceutical composition for oral administration to the subject" mean that the dosage form is a ***solid*** preparation, which is given to a patient as a solid, not a liquid.

2. Based on the clear meaning of "at least one," the phrase "at least one optional Secondary Essential Buffer" *requires* a second buffer in addition to the recited primary essential buffer.

3. The phrases "combining . . . with an aqueous medium" and "mixing . . . with an aqueous medium" each require mixing with an aqueous medium prior to administration to a patient.

ARGUMENT

I. LEGAL STANDARDS

A. General Claim-Construction Principles.

Because patent claims define the invention and determine a patentee's right to exclude, a district court construes patent claims as a matter of law to determine their meaning and scope. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976, 980 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996).

In *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005), the Federal Circuit, sitting en banc, discussed claim-construction principles in detail and provided guidance for district courts to follow when construing claims. The *Phillips* court noted that there is no "magic

formula" for conducting claim construction and instead identified a hierarchy for using intrinsic and extrinsic evidence to discern the meaning of claim language.[13] *Phillips*, 415 F.3d at 1324.

First, "[t]he claims themselves provide substantial guidance . . . ." *Phillips*, 415 F.3d at 1314. A patent's claims "define the invention to which the patentee is entitled the right to exclude." *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004). Therefore a district court should look to the words of the claims themselves to ascertain the scope of the patented invention. *Vitronics*, 90 F.3d at 1582. Furthermore, a court should generally assign claim language the ordinary and customary meaning it would have to a person of ordinary skill in the art at the time of the invention, *i.e.*, as of the effective filing date of the patent application. *Phillips*, 415 F.3d at 1313; *see Housey Pharms., Inc. v. AstraZeneca UK Ltd.*, 366 F.3d 1348, 1352 (Fed. Cir. 2004).

Second, a court may "rely heavily on the written description for guidance as to the meaning of the claims." *Phillips*, 415 F.3d at 1317. Indeed, proper claim construction requires examination of the patent's written description. *Phonometrics, Inc. v. N. Telecom Inc.*, 133 F.3d 1459, 1464 (Fed. Cir. 1998). The ordinary meaning of claim language is the meaning it would have to those skilled in the art after reading the entire patent, including the specification. *Phillips*, 415 F.3d at 1313. While a patentee may act as a lexicographer by clearly setting forth in the written description an explicit definition for a claim term, *see, e.g., Jack Guttman, Inc. v*

---

[13] The intrinsic evidence consists of two components: the patent and its prosecution history. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). A patent contains two parts: first, the written description; second, the claims. The prosecution history -- the rest of the intrinsic evidence -- contains the record of the proceedings before the Patent and Trademark Office and includes the prior art cited during examination and arguments, amendments and explanations made by the patentees to obtain allowance of the patent. *Phillips*, 415 F.3d at 1317; *Vitronics*, 90 F.3d at 1582. "Extrinsic evidence consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Markman*, 52 F.3d at 980.

Kopykake Enters., Inc., 302 F.3d 1352, 1360 (Fed. Cir. 2002), the patentee must demonstrate intent to deviate from a term's ordinary and customary meaning by expressing a different meaning in the written description "with reasonable clarity, deliberateness, and precision." *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1325 (Fed. Cir. 2002) (quoting *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994)). Vague or ambiguous statements in the written description do not suffice to alter a term's ordinary meaning. *W.E. Hall Co., Inc. v. Atlanta Corrugating, LLC*, 370 F.3d 1343, 1353 (Fed. Cir. 2004).

Claim construction also requires consideration of the patent's prosecution history. *Markman*, 52 F.3d at 980. A "patentee is held to what he declares during the prosecution of his patent." *Gillespie v. Dywidag Sys. Int'l, USA*, 501 F.3d 1285, 1291 (Fed. Cir. 2007).

Finally, extrinsic evidence is "less significant than the intrinsic record in determining 'the legally operative meaning of claim language.'" *Phillips*, 415 F.3d at 1317 (quoting *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 862 (Fed. Cir. 2004)). A district court *may* consider extrinsic evidence to assist it in understanding scientific principles and the technology at the time of the invention, *see Markman*, 52 F.3d at 980, and a court *may* employ extrinsic evidence for claim construction purposes. *Phillips*, 415 F.3d at 1317. But a court should *not* use extrinsic evidence to vary or contradict the meaning of claim language where the intrinsic evidence determines the meaning. *Markman*, 52 F.3d at 981; *Vitronics*, 90 F.3d at 1583-85.

II. A "SOLID" DOSAGE FORM DOES NOT INCLUDE A LIQUID

Patent, Claim	Term	Par's Proposed Construction	Plaintiffs' Proposed Construction
'346 patent, claims 24 and 57	"solid pharmaceutical composition in a dosage form"	A solid preparation that is administered orally to the subject. Such a preparation would not include powders that are combined with a liquid prior to administration to the subject.	A solid dosage form that is pharmaceutically acceptable for storage, shipping, and [oral]* administration, including a powder that can be combined with an aqueous medium and then orally administered. *the word "oral" is present in Plaintiffs' construction of claim 29 of the '988 patent and claim 1 of the '885 patent, but not present in Plaintiffs' construction of claims 24 and 57 of the '346 patent.
'988 patent, claim 29	"solid oral pharmaceutical dosage form"		
'885 patent claim 1	"solid pharmaceutical composition for oral administration to the subject"		

The disputed terms "solid pharmaceutical composition in a dosage form," "solid oral pharmaceutical dosage form," and "solid pharmaceutical composition for oral administration to the subject" mean that the dosage form is a ***solid*** preparation that is administered orally to the subject as a solid. Such a preparation would not include powders that are later combined with a liquid in order to administer a dose to a patient. Plaintiffs, on the other hand, propose that these terms include "a powder that can be combined with an aqueous medium and then orally administered." In short, Plaintiffs ask this Court to construe ***a solid*** to include ***a liquid***. In addition, Plaintiffs affix additional terms such as "for storage, shipping, and administration," to concoct a construction that is unsupported by any intrinsic evidence. Plaintiffs' proposed claim construction turns words with ordinary meaning into nonsense.

A. The Clear Language Of The Claims Dictates That "Solid" Excludes A Liquid.

The first place to look when determining the meaning of claim language are the claims themselves. Claims 24 and 57 of the '346 patent read:

> 24. A method for treating an acid-caused gastrointestinal disorder in a subject in need thereof, comprising: administering to the subject a **solid pharmaceutical**

composition in a dosage form that is not enteric-coated; wherein the composition comprises active ingredients consisting essentially of:

(a) a therapeutically effective amount of approximately 5 mg to approximately 300 mg of a non-enteric coated proton pump inhibitor selected from the group consisting of omeprazole, lansoprazole, rabeprazole, esomeprazole, pantoprazole, pariprazole, and leminoprazole, or an enantiomer, isomer, derivative, free base, or salt thereof; and

(b) a buffering agent in an amount of approximately 1.0 mEq to approximately 150 mEq selected from the group consisting of a bicarbonate salt of a group IA metal, a calcium salt, and a magnesium salt, wherein the buffering agent is in an amount sufficient to elevate gastric acid pH of the subject's stomach to prevent or inhibit gastric acid degradation of the non-enteric coated proton pump inhibitor and achieve sufficient bioavailability of the proton pump inhibitor in the subject to elicit a therapeutic effect.

57. A **solid pharmaceutical composition in a dosage form** that is not enteric-coated, comprising: active ingredients consisting essentially of:

(a) a therapeutically effective amount of a non-enteric coated proton pump inhibitor selected from the group consisting of omeprazole, lansoprazole, rabeprazole, esomeprazole, pantoprazole, pariprazole, and leminoprazole, or an enantiomer, isomer, derivative, free base, or salt thereof; and

(b) a buffering agent selected from the group consisting of sodium bicarbonate, and calcium carbonate, in an amount more than about 40 times the amount of the proton pump inhibitor on a weight to weight basis in the composition.

(emphases added to both claims).

Claim 29 of the '988 patent reads:

29. A non-enteric coated **solid oral pharmaceutical dosage form**, comprising:

(a) active ingredients consisting essentially of:

(i) a proton pump inhibitor (PPI) selected from the group consisting of omeprazole, lansoprazole, rabeprazole, esomeprazole, pantoprazole, pariprazole, and leminoprazole, and an enantiomer, isomer, free base, and salt thereof, in an amount of approximately 5 mg to approximately 300 mg; and

(ii) at least one Primary Essential Buffer and at least one optional Secondary Essential Buffer in a total amount of approximately 0.1 mEq to approximately 2.5 mEq per mg of proton pump inhibitor; and

(b) a pharmaceutically-acceptable excipient; wherein the dosage form is created by a method comprising:

i) blending the proton pump inhibitor, the Primary Essential Buffer, the optional Secondary Essential Buffer, and the pharmaceutically-acceptable excipient; and

> ii) formulating the proton pump inhibitor, the Primary Essential Buffer, the optional Secondary Essential Buffer, and the pharmaceutically-acceptable excipient into a powder, tablet, suspension tablet, chewable tablet, capsule, two-part tablet, two-part capsule, effervescent powder, pellet, granule or effervescent tablet. (emphasis added).

Claim 1 of the '885 patent reads:

> 1. A method of treating a gastric acid related disorder in a subject in need thereof, comprising: providing a **solid pharmaceutical composition for oral administration to the subject**, the composition consisting essentially of:
> (a) a therapeutically effective amount of at least one acid labile, substituted benzimidazole H+, K+ -ATPase proton pump inhibitor;
> (b) at least one buffering agent in an amount of about 0.1 mEq to about 2.5 mEq per mg proton pump inhibitor; and
> (c) one or more optional pharmaceutically acceptable excipients; *wherein at least some of the proton pump inhibitor is not enteric coated and the solid pharmaceutical composition has a total buffering agent to total proton pump inhibitor weight ratio of greater than 20:1;* and orally administering the pharmaceutical composition to the subject, wherein upon oral administration of the pharmaceutical composition to the subject, an initial serum concentration of the proton pump inhibitor greater than about 0.1 μg/ml is obtained at any time within about 30 minutes after administration of the composition.[14] (emphasis added) (italics in original).

A solid, by universal definition, is not a liquid. Otherwise, the term "solid" would be rendered meaningless. *Exxon Chem. Patents, Inc. v. Lubrizol Corp.*, 64 F.3d 1553, 1557 (Fed. Cir. 1996) (explaining that every word in a claim informs its meaning and scope; claims may not be construed in a manner that renders a claim term meaningless or superfluous).

In some cases, such as this one, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to laymen, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words. *See Brown v 3M*, 265 F.3d 1349, 1352 (Fed. Cir. 2001) (holding that the claims did "not require elaborate interpretation"). In such cases, general purpose dictionaries

[14] Claim language in italics indicates additions made pursuant to Reexamination No. 90/007,686.

may be helpful. *Phillips*, 415 F.3d at 1314. That a solid does not include a liquid is consistent with the common meaning of the word "solid." Indeed, Stedman's Medical Dictionary defines a "solid" as "[a] body that retains its form when not confined; ***one that is not fluid, neither liquid*** nor gaseous." *See Stedman's Medical Dictionary* Definition of "Solid," attached as Ex. E to Decl. of Fineman (emphasis added). Because the patentee has not imparted some other, unusual definition of the term "solid," the Court must look to the term's ordinary and customary meaning. *See Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 990 (Fed. Cir. 1999) (holding that a claim term will be accorded its ordinary meaning unless "the patentee has chosen to be his or her own lexicographer by clearly setting forth an explicit definition for a claim term").

Therefore, looking at the language of the claims, one should construe the word "solid" to exclude a liquid.[15]

B. The Other Claims Also Reveal That "Solid" Does Not Include "Liquid."

The patentee affirmatively chose to claim solid compositions in some claims and liquid compositions in others. "Differences among claims can also be a useful guide in understanding the meaning of particular claim terms." *Phillips*, 415 F.3d at 1314-1315 (citations omitted). These differences also support Par's construction that the disputed terms cannot encompass powders that are combined with a liquid prior to administration. *See, e.g., Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 910 (Fed. Cir. 2004). Solid and liquid pharmaceutical compositions are mutually exclusive. For example, unlike claim 57 of the '346 patent, which covers "[a] ***solid*** pharmaceutical composition," claims 90 and 94 recite:

[15] In addition, some of the claims call for a dosage form that is not enteric-coated. One of ordinary skill would understand that only a *solid* oral dosage form can be coated. This language further shows that the claims are meant to address solid dosage forms, because if the invention were a liquid, there would be no need to state "not enteric-coated."

> 90. A method of producing a liquid pharmaceutical composition comprising: combining the dosage form of claim 57 with an aqueous medium.
>
> 94. A method for administering a liquid pharmaceutical composition to a subject, comprising: combining the pharmaceutical composition as recited in claim 57 with an aqueous medium to form a suspension, and orally administering the suspension to the subject in a single dose without administering an additional buffering agent.[16]

As evidenced by a comparison of these three claims, the patentee knew how to recite a liquid pharmaceutical composition. To now construe the disputed terms that claim a solid as encompassing a liquid would conflict with the patentee's own use of the words "solid" and "liquid."

C. In The Specification, The Patentee Expressly Distinguished Between Solid And Liquid Dosage Forms.

The Court may rely heavily on the written description for guidance as to the meaning of the claims. *Phillips*, 415 F.3d at 1317. Here, the patentee expressly distinguished between solid and liquid dosage forms throughout the specifications of the '346, '988 and '885 patents. For example:

> Further, it would be desirable to have a proton pump inhibitor formulation which is convenient to prepare and administer to patients unable to ingest solid dosage forms such as tablets or capsules, which is rapidly absorbed, and can be orally or enterally delivered as a **liquid form or solid form.**[17]
>
> * * *
>
> The inventive composition can **alternatively** be formulated as a powder, tablet, suspension tablet, chewable tablet, capsule, effervescent powder, effervescent tablet, pellets and granules . . . **Similar to the liquid dosage form, the dry forms** can further include anti-foaming agents, parietal cell activators, and flavoring agents.[18]

[16] The '346 patent (JA-1), col. 43, ll. 51-53 and col. 49, ll. 1-6.
[17] The '346 patent (JA-1), col. 10, ll. 48-53; *see also*, the '988 patent (JA-3), col. 7, ll. 47-53; the '885 patent (JA-2), col. 8, ll. 3-8 (emphasis added).
[18] The '346 patent (JA-1), col. 11, ll. 24-32 (emphases added).

Thus, according to the patentee, one embodiment of the invention exists in a "solid" form *before* dissolution or suspension in an aqueous solution. This "solid" embodiment of the invention is orally administered to the subject without first combining it with a liquid or aqueous medium.[19] Because the patentee expressly made the distinction between "solid" and "liquid" compositions, it would be improper to construe the terms "solid" dosage form or "solid" pharmaceutical composition as including liquid forms. Accordingly, Par's proposed construction is consistent with the written description and the plain meaning of the words "solid" and "liquid."

D. During Prosecution, The Patentee Expressly Excluded Liquid Dosage Forms From The Meaning Of The Term "Solid" Dosage Forms.

As discussed above, claim construction also requires consideration of the patent's prosecution history, *Markman*, 52 F.3d at 980. Here, during reexamination of the '885 patent,[20] the patentee expressly excluded liquid dosage forms of the active ingredients from the "solid" dosage forms of the claims. Accordingly, the patentee should be held to "what he declare[d] during the prosecution of his patent." *Gillespie*, 501 F.3d at 1291.

During reexamination of the '885 patent, the patent examiner rejected claim 26 and related dependent claims as anticipated by a prior art article by Drs. Carroll and Trudeau.[21] But the patentee distinguished his invention from what Carroll and Trudeau discuss in the article. This is important, because Carroll and Trudeau describe a liquid dosage form of omeprazole and

---

[19] *See, e.g.*, the patentee's disclosure that "the formulations of the present invention can also be manufactured in concentrated forms, such as powders, capsules, tablets, suspension tablets and effervescent tablets or powders, **which can be swallowed whole** . . . ." The '988 patent (JA-3), col. 13, ll. 15-19; the '885 patent (JA-2), col. 21, ll. 59-63) (emphasis added).

[20] Reexamination No. 90/007,686.

[21] *See* Ex Parte Reexamination Req. No. 90/007,686 File History, Mar. 24, 2006 Office Action (JA-19), pp. 9-12 (citing Matthew Carroll MD & Walter L. Trudeau MD, *Nasogastric Administration of Omeprazole for Control of Gastric pH*, 10th World Congress of Gastroenterology, Los Angeles, 22:P Abstracts: Poster Presentations (Oct. 2-7, 1994) ("Carroll and Trudeau")).

sodium bicarbonate that was prepared by opening capsules of enteric-coated omeprazole, and crushing and mixing the contents in a sodium bicarbonate solution to create a liquid suspension.[22] The patentee argued that the liquid suspension Carroll and Trudeau created was "not a solid dosage form."[23] Thus, the patentee limited the scope of the term "solid" dosage form by expressly disclaiming liquid dosage forms to overcome the prior art. *See Biodex Corp. v. Loredan Biomed., Inc.*, 946 F.2d 850, 863 (Fed. Cir. 1991); *Liquid Dynamics Corp. v. Vaughn Co. Inc.*, 355 F.3d 1361, 1367-68 (Fed. Cir. 2004) (citing *Autogiro Co. of Am. v. United States*, 384 F.2d 391 (Ct. Cl. 1967).[24]

The patentee also characterized the claim language in other arguments to the patent examiner. In particular, the patentee responded to a rejection of what became claim 24 of the '346 patent by noting that this claim ". . . and its dependent claims, claims a solid pharmaceutical composition" and "**[t]his solid composition is then administered to the subject; no mixing or stepwise administration is required.**"[25]

Par's proposed construction, which excludes liquid dosage forms from the term "solid dosage form" is further supported by the patentee's definition of the phrase "dosage form." During prosecution of the '346 patent, the patentee expressly defined the phrase "dosage form" to mean the final, finished dosage form that is administered to a subject. Therefore, a final, finished dosage form that is a "solid" cannot be a "liquid" by the plain meaning of those words.

---

[22] *See* Carroll and Trudeau (JA-17).

[23] Ex Parte Reexamination Req. No. 90/007,686 File History, Sept. 13, 2006 Interview Summary (JA-16), p. 3.

[24] *See also, Spectrum Int'l, Inc. v. Sterilite Corp.*, 164 F.3d 1372, 1378-9 (Fed. Cir. 1998) ("[by] distinguishing the claimed invention over the prior art, an applicant is indicating what the claims do not cover.").

[25] The '346 Patent File History, Mar. 25, 2002 Response (JA-8), p. 37 (emphasis in original).

During prosecution of the '346 patent, the patent examiner rejected certain claims as anticipated under 35 U.S.C. § 102(b) by U.S. Patent No. 4,786,505 ("Lovgren").[26] Lovgren teaches a core tablet made of omeprazole and an alkaline substance where the core is subsequently coated with an enteric coating.[27] In response to the rejection, the patentee argued that Lovgren's core tablet was an "intermediate" form prior to the application of the enteric coat, which was not the final, finished form administered to the subject. The patentee's argument was clear and unambiguous:

> Importantly, none of the cited references teach the oral administration of the uncoated intermediate cores . . . The intermediate cores, therefore, are not "dosage forms" as claimed because **a "dosage form" is defined as a *completed* form of a pharmaceutical preparation**.[28]
>
> * * *
>
> The '**final dosage form**' of Lovgren is either an enteric coated tablet or capsule . . . Thus, the Lovgren '505 Patent does not teach dosage forms free of enteric coatings . . . ."[29]

The patentee repeated this argument numerous times during prosecution of the '346 patent.[30] Thus, the patentee defined the phrase "dosage form" to mean the final, finished dosage form that is administered to a subject.

The patentee reaffirmed this definition during prosecution of a pending application related to the '346 patent where the limitation "dosage form" was again at issue. The patentee stated that another reference "discloses enteric coated preparations that are not in a **finished solid dosage form** . . . ."[31]

---

[26] *See* '346 patent File History, Feb. 23, 2001 Office Action (JA-18), p. 4.
[27] *Id.* at col. 3, ll. 20-28 and ll. 36-51.
[28] The '346 patent File History, June 25, 2001 Response (JA-6), p. 82 (emphasis added).
[29] *Id.* at p. 83 (emphasis added).
[30] *See* The '346 patent File History, June 25, 2001 Response (JA-6), p. 81; p. 81; the '346 patent File History, Mar. 25, 2002 Response (JA-8), p. 43, 44.
[31] U.S. Appl. No. 10/797,374 File History, Mar. 21, 2007 Response (JA-15), p. 22-23 (emphasis added); *see also id.* at p. 17 ("Oishi does not disclose a **finished dosage form** having

The patentee expressly limited the scope of the term "dosage form" by defining it to include only final, finished dosage forms. *See Biodex*, 946 F.2d at 863; *Liquid Dynamics*, 355 F.3d at 1367-68. Accordingly, Par's proposed construction of the term "solid" dosage form, which excludes liquid dosage forms such as liquid suspensions, is proper. In particular, Par's construction accounts for the patentee's definition of the phrase "dosage form" as the final, finished dosage form that is administered to a subject. In other words, a final, finished dosage form that is in the form of a "solid" cannot -- by the plain meaning of the word "solid" -- include a liquid that is administered to a subject. In contrast, Plaintiffs' proposed construction is improper as it is inconsistent with the patentee's statements during prosecution.

Par's construction is consistent with the common and ordinary meaning of the term "dosage form." The FDA defines the term as follows: "A dosage form is the physical form in which a drug is produced and dispensed, such as a tablet, a capsule, or an injectable." *See* U.S. Food and Drug Admin., *Drugs@FDA Glossary of Terms*, http://www.fda.gov/Cder/drugsatfda/glossary.htm (last accessed August 19, 2008).

The term "solid" dosage form or pharmaceutical composition is a common limitation in the related '346, '988 and '885 patents and should be consistently applied to these patents. These patents share a common ancestry, and have specifications that consistently define "solid" dosage forms and "solid" pharmaceutical compositions as solids, not liquids. The meaning a patentee gives to a claim term during prosecution of one application may define common terms in related applications. *See Omega Eng'g, Inc, v. Raytek Corp.*, 334 F.3d 1314, 1333, 1335 (Fed. Cir. 2003); *Verizon Servs. Corp. v. Vonage Holdings Corp*, 503 F.3d 1295, 1307 (Fed. Cir.

---

omeprazole, at least a portion of which is not enteric coated. While Oishi discloses an intermediate core that is not enteric coated, the disclosed core is not a **finished dosage form**." (emphases added)).

2007); *see also Microsoft Corp. v. Multi-Tech Sys., Inc.*, 357 F.3d 1340, 1349-50 (Fed. Cir. 2004).

Accordingly, Par's proposed construction, which excludes liquid dosage forms, is informed by and consistent with the intrinsic record. In contrast, Plaintiffs' proposed construction is improper as it is wholly inapposite to the plain language of the claims and patentee's express statements in the intrinsic record.

III. THE '988 PATENT REQUIRES AT LEAST TWO BUFFERS.

The phrase "at least one optional Secondary Essential Buffer" requires a second buffer in addition to the recited primary essential buffer. Claim 29 of the '988 patent reads:

> 29. A non-enteric coated solid oral pharmaceutical dosage form, comprising:
> (a) active ingredients consisting essentially of:
> (i) a proton pump inhibitor (PPI) selected from the group consisting of omeprazole, lansoprazole, rabeprazole, esomeprazole, pantoprazole, pariprazole, and leminoprazole, and an enantiomer, isomer, free base, and salt thereof, in an amount of approximately 5 mg to approximately 300 mg; and
> (ii) at least one Primary Essential Buffer **and at least one optional Secondary Essential Buffer** in a total amount of approximately 0.1 mEq to approximately 2.5 mEq per mg of proton pump inhibitor; and
> (b) a pharmaceutically-acceptable excipient; wherein the dosage form is created by a method comprising:
> (i) blending the proton pump inhibitor, the Primary Essential Buffer, the optional Secondary Essential Buffer, and the pharmaceutically-acceptable excipient; and
> (ii) formulating the proton pump inhibitor, the Primary Essential Buffer, the optional Secondary Essential Buffer, and the pharmaceutically-acceptable excipient into a powder, tablet, suspension tablet, chewable tablet, capsule, two-part tablet, two-part capsule, effervescent powder, pellet, granule or effervescent tablet. (emphasis added).

The parties' proposed constructions regarding the disputed claim term "at least one optional Secondary Essential Buffer" are set forth below:

Term	Par's Proposed Construction	Plaintiffs' Proposed Construction
at least one optional Secondary Essential Buffer	at least one buffer in addition to the recited primary essential buffer, where such additional buffer is unsuitable for use alone because it produces too high a pH value leading to gastrointestinal mucosal irritation	a buffering agent that is not required in every formulation, but which can be combined with Primary Essential Buffers to produce a higher pH and added neutralization capacity for the formulation

The Federal Circuit has consistently held that the "[u]se of the phrase 'at least one' means that there could be only one or more than one" of that claimed element. *Rhine v. Casio, Inc.*, 183 F.3d 1342, 1345 (Fed.Cir. 1999). As such, a proper construction of this term requires that there be one or more than one Secondary Essential Buffer.[32] This construction is confirmed by the prosecution history.

During prosecution, the patentee relied on the requirement of a second buffer to overcome a prior art rejection, as well as to satisfy the requirements of 35 U.S.C. § 112.[33] Specifically, the patent examiner rejected originally filed claim 1, which recited only one buffer, as anticipated under 35 U.S.C. § 102(b) by the Oishi patent applications.[34] In response to the rejection, the patentee added "an optional Secondary Essential Buffer" to claim 1.[35] The patentee distinguished its alleged invention over the prior art on the basis that his claims require a second buffer:

> The claims have been amended to better define the invention. In particular, the nonenteric coated or non-delayed-release pharmaceutical dosage form comprises

[32] To the extent that Plaintiffs argue the word "optional" means that that a Secondary Essential Buffer is not required in every formulation, the patentee disclaimed such a construction in arguments he made to distinguish his alleged invention from the prior art. *See*, the '988 patent File History, Jul. 11, 2002 Response (JA-11), pp. 11-12.
[33] The '988 patent File History, Jul. 11, 2002 Response (JA-11), p. 11.
[34] The '988 patent File History, Feb. 1, 2002 Office Action (JA-10), at p. 2.
[35] The '988 patent File History, July 11, 2002 Response (JA-11), at p. 18.

> active ingredients consisting essentially of a non-enteric coated proton pump inhibitor, a Primary Essential Buffer, **and a Secondary Essential Buffer**. . . . As JP05194224 and JP05194225 [the Oishi applications] fail to disclose each and every element of the amended present claimed invention and fail to sufficiently describe the claimed invention to have placed the public in possession of it, the applicant submits that anticipation cannot be found.[36]

The patentee unequivocally characterized the claims as requiring at least two buffers.[37]

The requirement of at least two buffers was further emphasized when the patentee later amended claims 1 and 46 to recite: "at least one optional Secondary Essential Buffer" in response to a rejection under a 35 U.S.C. § 112, ¶ so as to "clearly define[] the metes and bounds of the invention."[38]

A patentee may surrender claim scope by voluntary amendment. *Norian Corp. v. Stryker Corp.*, 432 F.3d 1356, 1361-62 (Fed. Cir. 2005). Here, the patentee expressly limited the scope of the claim to require at least two buffers, *i.e.*, a Primary Essential Buffer and a Secondary Essential Buffer. *See Biodex*, 946 F.2d at 863; *Liquid Dynamics*, 355 F.3d at 1367-68.

Accordingly, Par's proposed construction is proper as it is supported by the intrinsic record and Plaintiffs' proposed construction is improper as it is contrary to the patentee's express statements and amendments during prosecution.

---

[36] The '988 patent File History, July 11, 2002 Response (JA-11), p. 11 (emphasis added).

[37] The requirement for two buffers is reinforced by how the Applicant chose to define and distinguish between Primary and Secondary Essential Buffers in his specification. The patentee indicated particularly that Secondary Essential Buffers do not play an important role in protecting the PPI from early acid-induced degradation. The '988 patent, col. 46 ll. 56-67. (JA-3). No buffer can be characterized as both a Primary and Secondary Essential buffer. Because the Applicant also characterized the claims as requiring both a Primary and Secondary Essential Buffer during prosecution, the claims require at least two different buffers. A single buffer could not fulfill the limitations of the claims.

[38] The '988 patent File History, Sept. 25, 2002 Office Action (JA-12), p. 2.

IV. THE RECITATION OF A LIQUID PHARMACEUTICAL COMPOSITION NECESSARILY REQUIRES THAT "COMBINING" AND "MIXING" A SOLID FORM WITH AN AQUEOUS MEDIUM BE CONSTRUED TO MEAN PRIOR TO ADMINISTRATION.

Claim 90 of the '346 patent requires a liquid pharmaceutical composition. Similarly, claim 3 of the '885 patent requires a liquid pharmaceutical composition when certain solid forms are mixed with an aqueous medium. Claim 90 of the '346 patent reads:

> 90. A method of producing a **liquid pharmaceutical composition** comprising: **combining** the dosage form of claim 57 **with an aqueous medium**. (emphasis added).

Claim 3 of the '885 patent reads:

> 3. The method of claim 1, wherein the **pharmaceutical composition** is in a form selected from the group consisting of a tablet, capsule, powder, suspension tablet, effervescent tablet or capsule, chewable tablet, granules, pellets, and a **liquid** created by **mixing** any of the foregoing **with an aqueous medium**. (emphasis added).

The parties' proposed constructions regarding the disputed claim terms "combining the dosage form" and "mixing . . . with an aqueous medium" are set forth below:

Patent, Claim	Term	Par's Proposed Construction	Plaintiffs' Proposed Construction
'346 patent, claim 90	"combining the dosage form of claim 57 with an aqueous medium"	requires combination with an aqueous medium prior to oral administration to the subject	requires combination with a medium that includes water
'885 patent, claim 3	"mixing . . . with an aqueous medium"	requires mixing with an aqueous medium prior to oral administration to the subject	requires mixing with a medium that includes water

One of ordinary skill understands that a "pharmaceutical composition" is the dosage form that is actually administered to a subject. Claim 90 of the '346 patent incorporates all the limitations of claim 57, and claim 3 of the '885 patent incorporates all the limitations of respective claim 1, each of which is directed to a "pharmaceutical composition." Therefore, both claim 90 of the '346 patent and claim 3 of the '885 patent are limited to the drug in the form as it is given to the

patient. *See Takeda Pharm. Co., Ltd, v. Teva Pharms. USA, Inc.*, 542 F. Supp. 2d 342, 348 (D. Del. 2008) ("'A pharmaceutical composition' means a medicinal drug product in a state suitable for administration to a patient."); *see also Ortho-McNeil Pharm., Inc. v. Kali Labs., Inc.*, 482 F. Supp. 2d 478, 499 (D.N.J. 2007) (construing pharmaceutical composition to mean "a medicinal preparation comprising an intimate admixture, ***prepared outside the body***, generally in the form of a dosage unit . . . .") (emphasis added). A liquid pharmaceutical composition is one that is administered to a subject in the form of a liquid. Accordingly, the phrases "combining" and "mixing" "with an aqueous medium" in claim 90 of the '346 patent and claim 3 of the '885 patent must be construed to occur prior to administration. In other words, the solid forms must be combined/mixed with an aqueous medium (such as water) outside of a subject's body to create a liquid pharmaceutical composition that is thereafter administered to the subject.

CONCLUSION

For the foregoing reasons, Par respectfully requests that the Court enter an order construing the terms and phrases of the '346, '885, and '988 patents as proposed by Par.

Of Counsel:
Edgar H. Haug
James K. Stronski
Bryan J. Braunel
Frommer Lawrence & Haug LLP
745 Fifth Avenue
New York, New York 10151
(212) 588-0800

Janine A. Carlan
Aziz Burgy
Timothy W. Bucknell
Arent Fox LLP
1050 Connecticut Ave., N.W.
Washington, D.C., 20036
(202) 857-6000

Frederick L. Cottrell, III (#2555)
Steven J. Fineman (#4025)
Richards, Layton & Finger, P.A.
One Rodney Square
920 North King Street
Wilmington, DE 19801
(302) 651-7700
Cottrell@rlf.com
Fineman@rlf.com
Attorneys for Defendant

Dated: August 22, 2008

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I hereby certify that on August 22, 2008, I electronically filed the foregoing document with the Clerk of Court using CM/ECF which will send notification of such filing(s) and Hand Delivered to the following:

Jack B. Blumenfeld, Esquire
James W. Parrett, Esquire
Morris, Nichols, Arsht & Tunnell LLP
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899-1347

Steven J. Fineman (#4025)
Richards, Layton & Finger, P.A.
One Rodney Square
P.O. Box 551
Wilmington, Delaware 19899
(302) 651-7700
fineman@rlf.com